UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

Case No. 22 C 4367

v.

MORTON GROVE PHARMACEUTICALS, INC., a Delaware corporation, and GOPALAKRISHNAN VENKATESAN, an individual,

Defendants.

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through undersigned counsel, respectfully represents as follows:

1. This statutory injunction proceeding is brought pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), to enjoin Morton Grove Pharmaceuticals, Inc., a Delaware corporation, and Gopalakrishnan Venkatesan, an individual (collectively, "Defendants"), from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce, drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and (b) violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while held for sale after shipment of the drugs or one or more of their components in interstate commerce.

Jurisdiction and Venue

2. Congress conferred upon district courts the authority to restrain such violations in 21 U.S.C. § 332(a). The court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

Defendants and their Operations

4. Defendant Morton Grove Pharmaceuticals, Inc. ("MGP") is a Delaware corporation incorporated in 1995. Since 2007, MGP has been a majority owned subsidiary of Wockhardt Limited. MGP's principal place of business is 6451 Main St, Morton Grove, IL 60053-2633, which is within the jurisdiction of this Court. MGP manufactures non-sterile prescription and over-the-counter finished drug products in the form of oral, topical, and nasal solutions, suspensions, and powders (collectively, MGP's "drug products") and distributes them to pharmaceutical wholesale distributors and large pharmacy chains.

5. Defendant Gopalakrishnan Venkatesan is the president of, and the most responsible person at, MGP.

Distribution of Drugs in Interstate Commerce

6. Defendants are engaged at 6451 Main St, Morton Grove, IL 60053-2633, in manufacturing, processing, packing, holding, and distributing a variety of products, including but not limited to Fluticasone Propionate Nasal Spray, Promethazine Syrup Plain, and Promethazine with Dextromethorphan Cough Syrup. All of MGP's drug products are articles of drug, within the meaning of 21 U.S.C. § 321(g)(1).

7. Defendants manufacture MGP's drug products using one or more components shipped in interstate commerce from places outside the State of Illinois, including, for example, Promethazine Hydrochloride, USP, which was shipped from Georgia, and liquid sugar, which was shipped from Indiana.

8. Defendants hold for sale MGP's drug products and ship them to places outside the state of Illinois, including for example, Promethazine with Codeine Oral Solution, which was shipped to Kentucky.

Defendants' Violations of the Act

9. The FDCA requires drug manufacturers to operate in compliance with current good manufacturing practice for drugs ("CGMP"). 21 U.S.C. § 351(a)(2)(B). The FDCA and FDA's CGMP regulations, 21 C.F.R. pts. 210 & 211, mandate that manufacturers control the processes and procedures by which drugs are manufactured, processed, packed, and held in order to ensure that drugs have the identity, strength, quality, purity, and other attributes necessary for their safe and effective use. Drugs not made in conformance with CGMP are deemed to be adulterated as a matter of law, regardless of whether they are deficient in any respect. 21 U.S.C. § 351(a)(2)(b); 21 C.F.R. § 210.1(b).

10. Five FDA inspections of MGP during the period starting December 6, 2010 and ending May 5, 2021 establish that the drugs that Defendants manufacture and distribute are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), because the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding are not in compliance with CGMP. 21 C.F.R. pts. 210 & 211.

11. FDA investigators most recently inspected MGP's facility in Morton Grove, Illinois, from April 19-May 20, 2021. During that inspection, FDA investigators documented many deviations from CGMP. At the close of the inspection, FDA investigators issued a list of inspectional observations ("Form FDA 483") to Defendant MGP. The CGMP violations observed during the inspection included, but were not limited to, the following:

A. Failure to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed, as required by 21 C.F.R. § 211.192, including the failure to reject drug lots after discovering the use of a contaminated component and the failure to fully investigate the root cause of the contamination;

B. Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b);

C. Failure to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements, as required by 21 C.F.R. § 211.67(a); and

D. Failure to establish and follow laboratory control mechanisms, as required by 21 C.F.R. § 211.160(a).

12. In a letter to FDA dated June 12, 2021, an MGP official represented that MGP was taking actions to correct the CGMP violations that the FDA investigators identified during their 2021 inspection. FDA reviewed the letter and determined that many of the firm's proposed corrective actions are not adequate to fully address the CGMP violations that the FDA investigators observed during their inspection.

13. MGP violates 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce its drug products, which are articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that they have been manufactured, processed, packed, or held in violation of CGMP, 21 C.F.R. parts 210 and 211.

14. MGP violates 21 U.S.C. § 331(k) by causing the adulteration of its drug products within the meaning of 21 U.S.C. § 351(a)(2)(B), while they are held for sale after shipment of one or more of their components in interstate commerce.

History of Noncompliance

15. MGP has a long history of violating the FDCA. Several of the CGMP deviations observed during the most recent inspection (referenced in ¶ 11 above) are similar to those that FDA investigators observed during prior inspections of MGP in August-October 2019, January-February 2016, January-March 2014, and December 2010-April 2011.

16. FDA's inspections, and the repeat violations observed, demonstrate MGP's unwillingness or inability to comply with the law. For example, FDA documented MGP's failure to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications (similar to the violation described in ¶ 11(A) above) on at least four earlier occasions; MGP's failure to establish adequate laboratory controls (similar to ¶ 11(B) above) on at least two previous occasions; MGP's failure to appropriately clean equipment and utensils (similar to ¶ 11(C) above) on one prior occasion, in 2019, when FDA investigators observed residue, chipped paint, and rust on equipment, and considering that MGP uses the same equipment to manufacture different types of products but does not have processes to ensure against product cross-contamination; and MGP's failure to establish and follow

laboratory control mechanisms (similar to ¶ 11(D) above) on one prior occasion. FDA inspectors documented numerous other CGMP violations at MGP during at least two FDA inspections.

17. MGP's noncompliance has continued despite repeated warnings from FDA. At the close of each of the five inspections of MGP that FDA conducted during the period starting December 6, 2010 and ending May 5, 2021, FDA investigators issued a detailed list of Inspectional Observations ("Form FDA-483") to the most responsible person at MGP, in which the FDA investigators detailed the deficiencies that they observed during their inspections. In each case, MGP responded to FDA either orally or in writing with promises to correct at least some of the CGMP violations. Although MGP made some corrections in response to FDA's inspectional observations, it either failed to correct others or failed to sustain the corrections it made, as shown by the FDA Investigators' observations and documentation of ongoing, serious CGMP violations on each successive inspection of MGP's facility.

18. FDA issued a warning letter to MGP in 2017, in which it described violations of the CGMP that FDA investigators observed during FDA's inspection of MGP during the period starting January 4 and ending February 5, 2016. In the Warning Letter, FDA emphasized the serious nature of the violations and alerted MGP that further regulatory action may result if MGP did not correct the deficiencies.

19. FDA held a regulatory meeting with MGP on November 20, 2014 to discuss the CGMP violations that FDA investigators observed during their January-March 2014 inspection of MGP. During this meeting, FDA stressed the importance of complying with all CGMP requirements and warned that if the violations were not corrected, FDA may pursue enforcement action.

20. Based on the foregoing, Plaintiff believes that Defendants will continue to violate the Act in the manner set forth above, unless the Court restrains them.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants MGP Venkatasan, and each of their officers, agents, representatives, employees, attorneys, and all persons in active concert or participation with any of them, from directly or indirectly doing any of the following acts:

a. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

b. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing drugs from MGP, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold drugs are established, operated, and administered in conformity with CGMP and the Act, in a manner that FDA finds acceptable.

III. Authorize FDA to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug or drug component, to ensure continuing compliance with the terms of the injunction, with the

costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such relief as the court deems just and proper, including equitable monetary relief.

Respectfully submitted,

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